REMARKS

Claims 1-33 are pending in the subject application, with claim 1, 29, 32 or 33 being in independent form.

Rejection under 35 U.S.C. §102(e)

In the October 3, 2003 Office Action, claims 1-33 were rejected under 35 U.S.C. §102(e) as purportedly anticipated by U.S. Patent No. 6,236,883 to Ciaccio et al. (hereinafter "the '883 patent").

Applicants filed, on December 31, 2003, a response to the October 3, 2003 Office Action, including the rejection of claims 1-33 under 35 U.S.C. §102(e).

The March 12, 2004 Official Communication issued by the PTO stated that Applicants' December 31, 2003 response does not particularly point out the specific claim language which defines the claimed invention over the applied art.

The following comments supplement the December 31, 2003 response filed by Applicants.

The '883 patent describes a method to detect and localize reentrant circuits using data acquired primarily during ventricular tachycardia. Ventricular tachycardia is an abnormal heart rhythm (arrhythmia) in which the heart beats very rapidly. The rapid beating is due to the fact that the electrical pathways for conduction are abnormal (circular pattern or reentrant circuit). In patients undergoing diagnosis and treatment, the clinician attempts to induce ventricular tachycardia using programmed electrical stimulation. However, this is not always possible, either because programmed electrical stimulation does not work or because the patient cannot hemodynamically tolerate any induced tachycardia. Therefore, a method was needed which

pinpoints reentrant circuits causing ventricular tachycardia without actually inducing the tachycardia.

The present application describes methods and apparatuses for identifying and localizing a reentrant circuit isthmus in a heart of a subject while acquiring data during (normal) sinus rhythm of the heart without induction of ventricular tachycardia. The new technology described in the present application which can be very useful to the clinician for treatment of ventricular tachycardia is neither disclosed nor suggested in the '883 patent.

Two new mapping procedures based on electrogram signals obtained from the heart of the subject during sinus rhythm were developed by Applicants and are described in the present application. The claimed invention describes generation of such maps and use of the maps to determine and display a location of the reentrant circuit isthmus in the heart.

One of the new mapping procedures developed by Applicants is the sinus rhythm activation gradient map. The activation gradient is the linear regression of activation times along a vector. The regression line is most uniform (highest r2 value) and sharpest gradient (steepest slope) at the location where the reentrant circuit isthmus (central location) will form during ventricular tachycardia. At this region also, there is the steepest slope of the regression line compared to surrounding regions. By mapping the regression lines for the set of all vectors in the mapped area, one can estimate where the center or isthmus of the reentrant circuit will form when ventricular tachycardia occurs. It is at this location that blockage of the conduction pathway (by imparting energy to the heart using a technique called catheter ablation) will block the abnormal electrical activity and prevent reinduction of ventricular tachycardia, i.e., the

patient is cured. It is potentially very important because presently the cure rate is only about 60%.

The other mapping procedure which Applicants developed is the electrogram duration map, i.e., a map of the duration, or width, of the deflection of the electrogram signal during each heart beat. Short electrogram duration tends to occur at the location coincident with the place where the isthmus of the reentrant circuit will form during ventricular tachycardia. At the boundary between short and long electrogram duration, the walls or perimeter of the reentrant circuit isthmus occur. Since the electrogram duration is a sinus rhythm measurement, it is not only possible to estimate the vector location over which the reentry isthmus will form, but its actual boundaries during ventricular tachycardia. This latter measurement is therefore potentially extremely useful to the clinician who is attempting to deduce the precise location and shape at which an ablation lesion should be made on the heart surface to prevent abnormal electrical conduction from leading to ventricular tachycardia.

Successful ablation means that the patient will no longer have episodes of spontaneous ventricular tachycardia. Such episodes are uncomfortable to the patient, can cause syncope (fainting) and can even lead to cardiac arrest. Normally, when ablative procedures fail, the patient must either undergo a lifelong regiment of antiarrhythmic drugs which can be expensive, are inconvenient, and may not be entirely effective, and/or must undergo surgery to remove the arrhythmogenic (abnormally conducting) tissue, which has some morbidity and mortality associated with the procedure.

Each of independent claims 1 and 29 of the present application is directed to a method for identifying and localizing a reentrant

circuit isthmus in a heart of a subject during sinus rhythm. The method of claim 1 includes the steps of (a) receiving electrogram signals from the heart during sinus rhythm via electrodes, (b) creating a map based on the received electrogram signals, and (c) determining, based on the map, a location of the reentrant circuit isthmus in the heart. The method of claim 29 includes the steps of (a) receiving electrogram signals from the heart during sinus rhythm via electrodes, (b) creating a map based on the received electrogram signals, (c) finding a center reference activation location on the map, (d) defining measurement vectors originating from the center reference activation location, and (e) selecting from the measurement vectors a primary vector indicating a location of the reentrant circuit isthmus in the heart.

Each of independent claims 32 and 33 of the present application is directed to a system for identifying and localizing a reentrant circuit isthmus in a heart of a subject during sinus rhythm. The system of claim 32 includes (a) an interface for receiving electrogram signals from the heart during sinus rhythm via electrodes, and (b) processing means for creating a map based on the received electrogram signals, and determining, based on the map, a location of the reentrant circuit isthmus in the heart. The system of claim 33 includes (a) receiving means for receiving electrogram signals from the heart during sinus rhythm via electrodes, (b) storage means for storing electrogram data corresponding to the electrogram signals received by the receiving means, and (c) processing means for retrieving the electrogram data, creating a map based on the electrogram signals, finding a center reference activation location on the map, defining measurement vectors originating from the center reference activation location, selecting from the measurement vectors a primary axis vector indicating a location of the

reentrant circuit isthmus in the heart, finding threshold points of the electrogram signals on the map, and connecting the threshold points to form a polygon indicating a shape of the reentrant circuit isthmus in the heart.

The '883 patent neither discloses or suggests use of a map, such as a sinus rhythm activation gradient map and/or an electrogram duration map, which is based on electrogram signals obtained from the heart of the subject during sinus rhythm, to determine and display a location of the reentrant circuit isthmus in the heart, as described in independent claim 1, 29, 32 or 33.

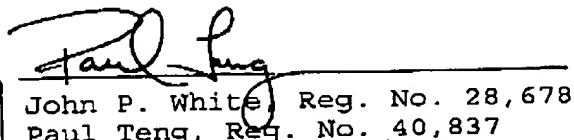
Accordingly, Applicants maintain that claims 1-33 are allowable over the cited art, and earnestly solicits the allowance of this application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone them at the telephone number provided below.

If a petition for an extension of time is required to make this response timely, this paper should be considered to be such a petition, and the Commissioner is authorized to charge the requisite fees to our Deposit Account No. 03-3125.

If any additional fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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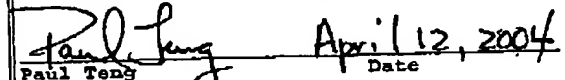
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



April 12, 2004
Date

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